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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/788,051 | 02/16/2001 | Shubhada D. Godbole | HYS-39 | 6652 |

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| EXAMINER | |
|---|---|
| LI, QIAN JANICE | |
| **ART UNIT** | **PAPER NUMBER** |
| 1632 | |

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/788,051 | GODBOLE ET AL. | |
| | Examiner | Art Unit | |
| | Q. Janice Li | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *16 February 2001*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

I. Claims 1-8, 13-15, 23, and 25-27 are drawn to an isolated polynucleotide selected from the group consisting of SEQ ID Nos: 2, 3, 5 or a polynucleotide encoding SEQ ID Nos: 4, 6-15, complements, variants or portions of the polynucleotide, a genetic construct containing the polynucleotide, and host cells comprising the polynucleotide, a composition containing the polynucleotide, and a method for producing a polypeptide using the host cell. Classified in class 536, subclass 23.1, and class 435, subclass 320.1, 325, and 455.

II. Claims 9-12 and 24 are drawn to an isolated polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID Nos: 4, and 6-15, variants or portions of the polypeptides, and a composition or kit comprising the polypeptides. Classified in class 530, subclass 350.

III. Claim 16 is drawn to an antibody that binds to a polypeptide of SEQ ID Nos 4 or 6 or a portion thereof. Classified in class 530, subclass 387.1.

IV. Claims 17-19 are drawn to a method for detecting a polynucleotide comprising contacting a sample with a compound that binds to and forms a complex with the polynucleotide Classified in class 435, subclass 6.

V. Claim 20 drawn to a method for detecting a polypeptide comprising contacting a sample with a compound that binds to and forms a complex with the polypeptide Classified in class 435, subclass 7.1.

VI. Claim 21 is drawn to a method for identifying a compound that binds to the polypeptide using a cell free method. Classification is to be determined.

VII. Claim 22 is drawn to a method for identifying a compound that binds to the polypeptide using a cell assay method. Classified in class 435, subclass 6.

VIII. Claim 28 (a) is drawn to a method for enhanced activity of cadherin-like polypeptide comprising administering a therapeutic amount of an agonist of said polypeptide. Classification is to be determined depending on the nature of the agonist.

IX. Claim 28 (b) is drawn to a method for enhanced activity of cadherin-like polypeptide comprising administering a therapeutic amount of said polypeptide. Classified in class 514, subclass 2.

X. Claim 28 (c) is drawn to a method for enhanced activity of cadherin-like polypeptide comprising administering a therapeutic amount of said polynucleotide encoding the polypeptide. Classified in class 514, subclass 44.

XI. Claim 29 (a) is drawn to a method for enhanced activity of cadherin-like polypeptide comprising administering a therapeutic amount of an antagonist to said polypeptide. Classification is to be determined depending on the nature of the antagonist.

XII. Claim 29 (b) is drawn to a method for enhanced activity of cadherin-like polypeptide comprising administering a therapeutic amount of a nucleic acid molecule that inhibits the expression of said polynucleotide encoding the polypeptide. Classified in class 514, subclass 44.

XIII. Claim 29 (c) is drawn to a method for enhanced activity of cadherin-like polypeptide comprising administering a therapeutic amount of a polypeptide that competes with said cadherine-like polypeptide. Classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II, III and I are independent and distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, invention groups I-III are drawn to different products, i.e. nucleic acids, proteins, and antibodies. The different products have distinct chemical structure and mode of operation, belong to different chemical entities.

Inventions IV-XIII and I are independent and distinct inventions. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, these inventions are drawn to different methods for producing polypeptides, for diagnosis and screening assays, and for

treatment of a subject. The different methods have different method steps, use different starting materials, achieve different goals, and require distinct technical considerations.

Inventions X and I could be related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for treatment could be practiced using a polypeptide or an agonist of said polypeptide, whereas the product of group I could be used for producing a polypeptide or for drug screening, gene regulation, and making a transgenic animal, etc.

Inventions VI, VII, IX, and II could be related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the polypeptide could be practiced using a polynucleotide or an agonist of said polypeptide, whereas the product of group II could be used for treatment or for various drug screening assays.

Inventions V and III could be related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). In the instant case, the process for detecting the polypeptide could be practiced using a ligand or a compound that binds to the polypeptide, whereas the antibody could be used for another process such as treatment of a subject.

Claims 28 and 29 require the use of an agonist or antagonist of the adherine polypeptide. It is noted that the claims encompass a large number of molecules that may act as a candidate for such agonist or antagonist, these molecules may not share a substantial structural feature essential to a common utility, and may have different mode of operation in a subject. In addition, a person of ordinary skill in that art would not envision one in view of the other. Accordingly, if one of the method for using the chemicals is elected, further identification of the chemical is necessary. Please note that this is an election of invention not a species election.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The differences of the Inventions I-XIII are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Q. Janice Li
Primary Patent Examiner
Art Unit 1632

QJL
August 20, 2004